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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,024	06/26/2001	Guolin Cai	00-432-A	1826

7590 11/05/2002

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EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 11/05/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,024	CAI ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9, 11-12, 14-16, 18,-19, 27-28, 30-34, 37, 40, 45-51, 53-70, 74-81* is/are rejected.

7)☒ Claim(s) *82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,9, 11-12, 14-16, 18,-19, 27-28, 30-34, 37, 40, 45-51, 53-70, 74-82.

1.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9, 11-12, 14-16, 18,-19, 27-28, 30-34, 37, 40, 45-51, 53-70, 74-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals R8 and R9 forming all heterocycloalkyl rings having from 5 to 8 ring atoms and where 1 or 2 of the ring atoms are selected from N, S, O, with remaining ring members being carbon, CH or CH2, which heterocycloalkyl ring is unsubstituted or substituted with one or more independently selected R4 groups; NRaRb forming all monocyclic or bicyclic rings each of which may contain one or more double bonds, or one or more of oxo, O, S, SO, SO2, NH or N(R2), wherein R2 is defined above and independently selected at each occurrence, Q equal to pyridinyl optionally substituted with one or more of R4, W is aryl substituted with one or more R3; in claims 74-80, W equal to all heteroaryl, and heterocycloalkyl groups which can be unsubstituted or substituted with one or more R3. Heteroaryl or aryl rings can not support electron withdrawing groups in the ortho position as is claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of

enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could

not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7th and 8th wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification, an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on signal-transducing activity of GABAa receptors .

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Claim(s) 54-66 in part are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. A method for altering the signal-transducing activity of GABAa receptors is a mechanism, not a disease. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or

have the applicants supplied the supporting data. The applicant is referred to ***In re Fouche*** 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte Foreman*** 230 USPQ 546 (Bd. Of App. And Inter 1986).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,9, 11-12, 14-16, 18,-19, 27-28, 30-34, 37, 40, 45-51, 53-70, 74-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 67-70 are indefinite for being improper product use claims. Applicant is referred to Clinical Products v. Brenner -Commissioner of Patents) 149 USPQ 475 (District Court DC 66) Ex parte Dunki 153 USPQ 678 (Bd of Appeals 1967).

B. In claim 1, lines 10-11, page 3 and all other occurrences throughout the claims 1, 9-62, 67-70, and 74-80, "is unsubstituted or substituted with one or more R3" is indefinite because there is no upper limit.

C. In claim 1, lines 12-13, page 3 and all other occurrences throughout the claims 1, 9-62, 67-70, and 74-80, "is unsubstituted or substituted with one or more R4" is indefinite because there is no upper limit.

Claim 82 is objected to because it is based on a rejected claim.

The IDS filed 6/19/02 has been considered. The references that have been crossed out will not be considered until provided to the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson
October 31, 2002

Alan L Rotman
ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600